November 16, 1999

"Straw Proposal" for Discussion Purposes

Framework
for a
Voluntary Children's Chemical Safety Testing Program

Introduction/Disclaimer

This draft, partially complete document has been prepared by EPA after careful consideration of all information presented orally and in writing at the September 22, 1999 Stakeholders meeting, all materials submitted to the associated dockets, and other information available to EPA. This document does not represent EPA's final position on any matter related to this voluntary testing initiative – it is simply a starting point for additional comment and discussion. This document has been prepared for the November 30 - December 1, 1999 stakeholder meeting, at which EPA **would like to focus on initial chemical selection criteria, the role of exposure information and test battery issues.** EPA has deferred consideration of "framework" issues (e.g. specific procedures for administration of a voluntary program) to the January 2000 meeting.

Background -- The Chemical Right-to-Know Children's Health Testing Challenge

On April 21, 1998, Vice President Gore, as part of his Chemical Right-to-Know announcement, committed EPA to "....review and report on what new testing may be needed to assess the special impact industrial chemicals may have on children." EPA believes that this initiative's focus is the testing of chemicals for their effects on children and prospective parents and that the scope of the effort does not extend to other public health issues associated with children such as lead poisoning, fetal alcohol syndrome, dietary concerns, etc. These important issues are for the most part addressed by or are the responsibility of other federal and state programs.

In initiating any testing program, decisions need to be made regarding the appropriate chemicals to test and the appropriate toxicology studies to conduct. To address these issues, EPA has initiated a stakeholder involvement process to bring together individuals with a broad range of interests in children's health issues to provide input into the design a voluntary program to obtain needed test data. Details of this process can be found at www.epa.gov/chemrtk. This document details EPA's current thinking with regard to the design of such a voluntary testing program. In this program, EPA will be soliciting chemical manufacturers (including importers)

to volunteer to conduct identified needed testing.

Rationale for Key Program Design Features

While EPA would prefer to proceed with a testing program that applies a single tier of tests to a set of approximately 50 chemicals (the approach taken by EPA in developing a proposed rule applying the test battery presented for peer review to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP)), it is clear that several stakeholders are unlikely to accept this approach via a voluntary scheme. One of the recommendations made by the SAP was: "EPA's goal should be to get a consistent set of data on 50 - 60 chemicals where there is reason for special concern, then re-evaluate the value of the tests". The SAP's rationale was that this number of chemicals would provide a sufficient body of data that could be used to reevaluate the battery in the future. EPA is committed to the extent possible to developing a workable, voluntary alternative to a test rule and therefore is open to the concept of including tiering approaches and exposure assessment as components of the program. However, for such an approach to be acceptable, several program design features or principles are essential:

1. HPV Challenge (or SIDS) data alone are not sufficient to support dropping a chemical for higher tier testing if there are indicators of high potential exposure. The HPV Challenge battery of tests was designed to identify chemicals that have relatively high toxicological activity as a priority for additional testing and/or risk management. The HPV Challenge battery does not have the sensitivity to confidently rule out potential risk concerns for low or moderate hazard chemicals with large exposures. Recognizing the potential for misleading, or as some stakeholders have described "false negative", results from the screening level studies included under the HPV Challenge is a key consideration in the design of the voluntary children's chemical safety testing program.

2. The debate over how to initially select chemicals should not delay the start of this testing initiative. Furthermore, the findings required under TSCA § 4 to promulgate a test rule to obtain the sought after data do not require an exposure assessment – only specific indications of potential exposure. EPA believes that a substantially more rigorous initial chemical selection procedure than one required to promulgate a test rule should be unnecessary.

3. Hazard data being sought by this program are relevant to an understanding of the inherent toxicological properties of a specific chemical and can be useful in assessing the risks associated with a variety of exposure scenarios. Exposure data, on the other hand, do not represent inherent properties of a chemical and have site- or use- specific relevance. Because of the inherent nature of toxicity data, EPA believes it is important for this program, once it has identified chemicals with a potential for high exposure to children

and/or prospective parents, to obtain hazard data on those chemicals unless it can be shown via appropriate information that exposures are considerably less than suggested.

4. Tiering can be applied for any number of reasons such as: economic considerations, policy considerations, recognition of scientific or biological knowledge or other reasons. In this case, EPA's analysis, which was supported by the SAP in its review, indicates that the understanding needed to support triggers based on biology does not presently exist. The information available to support the use of specific exposure elements as triggers is also limited at present. The net result of the limitations in the available information and understanding may be relatively uncertain triggers which must be applied with caution to provide assurance against decisions based on false negatives. As tiers and triggers are proposed, the underlying rationales should be made apparent.

5. The incorporation of tiering, triggering and exposure assessment into the testing scheme necessitates that more chemicals be included in the program. EPA, taking the SAP's guidance, would like to implement a program which takes about 50 chemicals through the entire scheme. Because the voluntary program will likely apply tiering and triggering, the number of chemicals entering the program will need to increase beyond what was originally contemplated in OPPT's test rule to ensure the development of sufficient data to evaluate the program as suggested by the SAP. Increasing the number of chemicals at the start of the program, to perhaps some number greater than 100, would shift the program from an absolute evaluation scheme (50 high exposure chemicals fully evaluated), to a relative evaluation scheme covering a larger number of chemicals in order to identify the ones which are most in need of a higher level of testing. This latter scheme would also seem to ease the strain on triggering, because a trigger would not necessarily lead to a "drop" decision but could lead to a "relatively lower priority" decision.

6. After chemicals with high potential exposure are initially selected for the program, exposure and hazard data should not be used to trigger the need for additional testing (i.e., a problem would need to be demonstrated) but should operate to support a conclusion that higher tier testing is not needed or is of lower priority for a given chemical. In most cases, testing would progress to higher tiers in absence of compelling exposure data demonstrating a lack of need for more testing. Generally, EPA believes it would be more protective to use exposure arguments to trigger dropping chemicals rather than to use exposure data to trigger additional testing.

7. It would be prudent for a trigger to apply across the tier -- i.e. if a positive hazard trigger is encountered in one or more tests, it leads to a chemical being a candidate for the entire next tier of testing. Thus, only chemicals presenting consistent negative responses across a given testing tier are viewed as having a lower priority. The argument for structuring the trigger in this way is that high potential exposure to children and/or prospective

parents is the driver and such a trigger helps to deal with limitations in the understanding of the biology of the triggers and with false negative issues. Chemicals with more positive responses would be considered higher priority.

8. The evaluation of "sufficient levels" of exposure resulting from food, drinking water, air, soil, children's products, and in children's tissues to justify additional testing as suggested in the Chemicals Manufacturers Association (CMA) proposal, may be more effective if the opposite, i.e. "insufficient levels", were used to support "dropping" higher tiers of testing. The extent to which exposure parameters could be used will depend on the availability of relevant information. At present, however, the availability of such exposure data are clearly limited and their development would require substantial time and resources. Consequently, EPA believes that the tiered approach should begin with readily available data indicating the potential for high exposure to children or prospective parents, but which are followed by industry efforts, or the efforts of other stakeholders, to develop more direct quantitative or definitive evidence of exposure to children.

Initial Chemical Selection Considerations

Both EPA and the CMA, to a large extent, agree that chemicals selected for the voluntary children's health chemical testing program would in most instances likely be HPV chemicals. CMA and other stakeholders have raised the issue of non-HPV chemicals -- the program should include such chemicals where warranted based on exposures or other considerations. EPA agrees that this testing program need not be limited a priori to HPV chemicals.

The primary data used by EPA to select chemicals for its draft test rule and to justify exposure-based findings at least qualitatively track fairly well with CMA's proposed exposure indicators to select chemicals for this voluntary program --- i.e. there is more agreement on the kinds of chemicals of concern than is readily apparent:

CMA	EPA
presence in foods children eat and drink	unregulated drinking water contaminants pesticide inerts large Toxic Release Inventory(TRI) releases chemicals in breast milk
presence in air, including residences/schools	large TRI releases Source Ranking Database (SRD) consumer chemicals indoor air monitoring data

presence in products in available forms	SRD consumer chemicals
presence in soils	large TRI releases
presence in tissues	high frequency in blood samples

In addition, the Children's Environmental Health Network (CEHN) has suggested including Persistent/Bioaccumulative/Toxic (PBT) chemicals as a group of chemicals targeted by this initiative. EPA agrees with the inclusion of PBT considerations as a useful addition to the chemical selection scheme.

EPA recognizes that the chemical selection criteria used during the development of a test rule are constrained by the statutory requirements for promulgation of regulations under TSCA. In a voluntary program many of these constraints need not necessarily apply. In an effort to be responsive to stakeholder interests in chemical selection, EPA is presently working on developing a tool that will encourage even more robust discussions on the chemical selection criteria. This tool is essentially a database with sets of different chemicals derived from various selection criteria and relevant data sources that could allow for consideration and discussion of several additional options regarding the criteria for chemical selection. Both HPV and non-HPV chemicals will be included. EPA will endeavor to incorporate appropriate information into the tool from the Endocrine Disruptor Priority Setting Database which is currently under development at EPA. Chemical sets included in the database tool will include:

Chemicals in Foods Children Eat and Drink as defined by:
- Chemicals in Breast Milk
- Pesticide Inerts in Food Use Pesticides
- FDA List of Indirect Food Additives
- National Contaminant Occurrence Database (includes unregulated drinking water contaminants)

Chemicals in Air Children Breathe as defined by:
- Chemicals in Consumer Products with Releases to Indoor Air (SRD)
- Chemicals with Large TRI Air Releases
- National Human Exposure Assessment Survey (NHEXAS)
- Total Exposure Assessment Methodology (Team)
- Aerometeric Information Retrieval System (AIRS)
- EPA Office of Research and Development studies and other published indoor air data

Chemicals in Available Forms in Products Children Use as defined by:
- Chemicals in Consumer Products with Releases to Indoor Air (SRD)

Chemicals in Soil and Dust as defined by **:**
- Pesticide Inerts
- Chemicals with Large Total TRI Air Releases
- Superfund Contract Laboratory Program

Chemicals in Human Tissues (including blood) as defined by:
- National Health and Nutrition Examination Survey III (NHANES)
- National Human Adipose Tissue Survey (NHATS)
- NHEXAS
- TEAM

Other data sets that may be relevant to chemical selection include:

Chemical Production Volume Data
- TSCA Inventory Update Rule
- HPV Challenge Chemical List

High Release Chemicals as defined by:
- Chemicals with Large Total TRI Releases

High Potential Worker Exposure as defined by:
- Chemicals with Large Numbers of Potentially Exposed Workers as Reported by NIOSH's National Occupational Exposure Survey (NOES)

Chemicals in the Above Datasets that have Physical/Chemical Properties Indicating that they may Persist and Bioaccumulate:
- Chemical Octanol-Water Coefficients
- Chemical Bioconcentration Factors (BCF)
- Chemical half lives in air
- Chemical half lives in soil
- Chemical half lives in water

A brief description of many of the datasets listed above is provided in Appendix 1 of this document.

EPA would like to receive feedback on additional existing sources of exposure information and additional data sets that could be developed for selection purposes. EPA is also interested in stakeholder discussion regarding the intersections or unions of the above data sets

which would be most appropriate to select candidate chemicals for the first tier testing consideration for the voluntary program. In addition, it may be desirable to weight the importance of certain datasets in a chemical selection process. EPA believes that the number of chemicals initially selected for the voluntary program should be some number greater than 50, for reasons outlined above. EPA is interested in stakeholder discussion on this point.

EPA would also like to consider approaches for supplementing the above chemical selection method by including an open process for stakeholders to nominate and provide the rationale for including candidate chemicals for the program.

Test Battery

EPA has undertaken significant technical efforts with regards to the test battery issue over the last year. The FIFRA Scientific Advisory Panel and invited members of the EPA Science Advisory Board (SAB) convened in late May to review the recommendations of the Toxicology Working Group of the 10X Task Force. The Toxicology Working Group had developed recommendations for a core data set necessary to assess the potential hazards to children following exposure to conventional food use pesticides. These recommendations were prepared for consideration in developing the implementation policy for the Food Quality Protection Act (FQPA) tenfold Safety Factor. OPPT sought input and advice from this EPA advisory group specifically about the appropriateness of using a selected subset of the 10X battery for this TSCA-related purpose. The SAP's comments were positive with respect to EPA's proposed test battery. Furthermore, the SAP supported the application of the battery as a single tier and thought a testing effort including about 50 chemicals would provide a sufficient body of data that could be used to reevaluate the battery in the future.

Although questions related to developmental neurotoxicity assay have been raised, such as the state of its validation, EPA has heard little from stakeholders indicating that other specific studies included in the test battery presented to SAP are inappropriate. The studies identified in the SAP process are the studies included in this program's test battery. On the other hand, EPA has heard frequently and forcefully from numerous stakeholders that several of the studies should be initiated only after "triggers" indicating concern have been tripped in lower level (e.g., HPV Challenge) tests.

The HPV Challenge test battery is recognized as a first step in acquiring hazard data on industrial chemicals and it appears that many stakeholders would like to build off the HPV Challenge and integrate activities from this initiative with this voluntary program. This integration would accommodate the Humane Society of the United States (HSUS) comments by ensuring that the children's health testing initiative takes advantage of the animal welfare considerations developed for the HPV Challenge. As noted above, however, reliance on the

HPV Challenge level of testing presents large issues regarding false negatives for chemicals with high exposure potential.

Recognizing the above science and policy input and the key program design features discussed earlier, EPA believes that it may be appropriate to revise CMA's proposed tiering structure by considering:

- the HPV Challenge tests as part of a 1st tier of tests with the understanding that this voluntary program includes an obligatory 2nd tier of testing for the subset of the initially selected chemicals which presents the relatively greatest priority. EPA suggests that this subset should include about 50 chemicals. It should be noted that the full HPV Challenge data package need not be in hand to initiate higher tier Children's testing (particularly instances in which higher tier testing supersedes HPV Challenge testing). Candidate chemicals for this program may need to be expedited in the HPV Challenge so that it does not become a substantial rate limiting step to progress on children's chemical safety testing.

- establishing a 2nd tier containing prenatal developmental toxicity (2 species), 2-generation reproductive toxicity, developmental neurotoxicity, mutagenicity, metabolism/pharmacokinetics, genotoxicity and subchronic (90-day) toxicity. This structure has several benefits in that it focuses the 2nd tier tests on studies which, for the most part, involve young animals and provides in this tier an alternative trigger for carcinogenicity based on the mutagenicity and subchronic results. EPA believes developmental neurotoxicity, a highly relevant test for assessing children's risks, should be a second tier study. CEHN strenuously pointed out that developmental neurotoxicity should be in the core toxicology set and should not be a triggered or a conditional test.

- establishing a 3rd tier containing carcinogenicity, adult neurotoxicity, and immunotoxicity.

The guideline numbers for the tests suggested by EPA for the 2nd and 3rd tiers are shown in Tables 1 and 2:

Table 1: Tier 2 Studies for Children's Health Effects

Test	Test Guideline
if not completed in the HPV Challenge: 90 day subchronic in rodents	870.3100 (oral)[1] 870.3250 (dermal)[1] 40 CFR 799.9346 (inhalation)
if not completed in the HPV Challenge: mammalian bone marrow chromosomal aberrations, OR mammalian erythrocyte micronucleus, OR in vitro mammalian chromosomal aberration test	 40 CFR 799.9538 40 CFR 799.9539 40 CFR 799.9537
in vitro mammalian cell gene mutation test in L5178Y mouse lymphoma cells	40 CFR 799.9530
prenatal developmental toxicity (2 species)	40 CFR 799.9370
reproduction and fertility effects	40 CFR 799.9380
developmental neurotoxicity	870.6300[1]
metabolism and pharmacokinetics	40 CFR 799.9748

Table 2: Tier 3 Studies for Children's Health Effects

Test	Test Guideline
carcinogenicity OR chronic toxicity/carcinogenicity	40 CFR 799.9420 870.4300[1]
neurotoxicity screening battery	40 CFR 799.9620
immunotoxicity	40 CFR 799.9780

[1]Rules establishing these Test Guidelines under 40 CFR 799 are expected to be promulgated by the end of 1999.

The question of the need for multiple exposure routes for testing needs to be discussed. CMA proposed testing only in the route of most concern. Physiologically based pharmacokinetics (PBPK) testing may help as an alternative to multiple route testing. CEHN has stated that the testing should include the dermal route of administration because it believes dermal exposure is an important exposure route for children. EPA would like to receive additional discussion on this point as the program design moves forward.

Testing Triggers and the Role of Exposure Information

Applying the chemical selection database tool described above EPA would identify 150 - 200 chemicals presenting the relatively greatest potential for exposures that may impact children.

It has been suggested that screening level exposure assessments developed using information such as that obtained under the Use and Exposure Information Project (UEIP) would be relevant to this voluntary program. Since UEIP was designed to be coupled with SIDS screening level hazard data, EPA believes that an exposure assessment based on UEIP quality data (particularly if data directly relevant to children's exposures is included) may contain sufficient detail to be effectively used with HPV Challenge data as the 1st tier in the scheme. The decision to proceed with the 2nd tier would be based on the assessment of chemicals' exposure prepared by the sponsor company, and supplemented as the sponsor company sees fit. To establish whether a chemical is a priority for 2nd tier testing, EPA's review would attempt to establish an initial set of about 50 chemicals presenting the greatest priority based on consideration of exposure information and, to a lesser extent, hazard information. EPA's review of exposure information would endeavor to identify, from the greater than 100 initially selected candidate chemicals, groups or bands of chemicals with roughly similar potential for children's exposure. For this approach to be successful consistency of the quality of exposure assessments would be important. Therefore, a common understanding of what constitutes a complete and "conservative" assessment would be desirable. The approximately 50 higher priority chemicals would then undergo 2nd tier testing and development of more quantitative exposure information, possibly including monitoring data.

EPA believes that the triggers to move chemicals from the 2nd to the 3rd tiers should be applied across the whole tier such that if a positive hazard trigger is encountered in at least one 2nd tier test, a chemical is considered a candidate for the 3rd tier. To the extent that more than one positive result is obtained in the 2nd tier tests, there is an even greater presumed need to consider higher tier testing. The hazard triggers described in the CMA proposal provide a useful starting point for discussions regarding the specific adverse effects that should be used to trigger the 3rd tier of the testing scheme described above. The CMA proposal also uses exposure data as one of the factors triggering further testing. Generally, EPA believes it would be more protective to use exposure arguments to trigger **dropping** chemicals rather than to use exposure

data to trigger additional testing. Thus, in the face of a positive result in the 2nd tier, given the high exposure potential of the chemicals in question, a decision not to pursue higher tier tests needs to be justified by more quantitative or definitive data showing a lack of exposure.

The decision not to proceed with a third tier (carcinogenicity, adult neurotoxicity, and immunotoxicity) would be triggered by 2nd tier testing results and more detailed assessment of relevant exposure information. To establish whether a chemical is of low priority for 3rd tier testing, EPA's review would consider calculated margins of exposure and a risk characterization to determine whether or not the chemical is appropriately considered a low priority for **children's risk**.

A schematic of the proposed testing scheme, triggering process and the role of exposure information in the program is shown in Figure 1.

Major Issues for Discussion at the November 30 - December 1 Stakeholder Meeting:

- Are the key program design features clear and appropriate? Are there other design features that need to be considered?

- Are the criteria identified for the initial selection of candidate chemicals appropriate? Are the datasets for chemicals selection useful and sufficient? Is the database tool a useful mechanism for identifying candidate chemicals?

- Are the studies appropriate for each tier? Have studies been omitted that need to be considered? Are there other combinations of tests for each tier? If so, what is the benefit of the revision?

- Is the approach proposed for triggering higher tier tests appropriate?

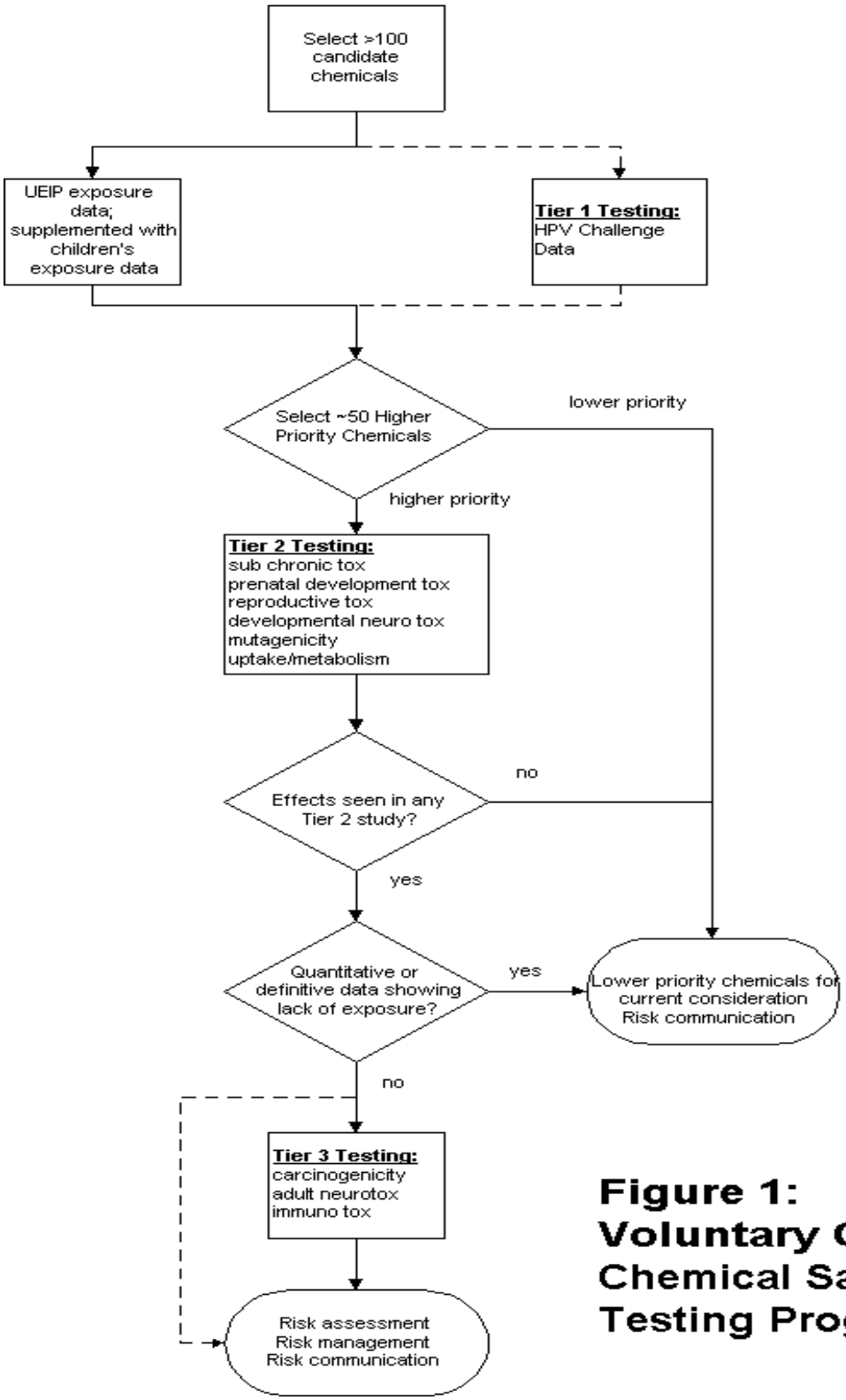

Figure 1: Voluntary Children's Chemical Safety Testing Program

Relationship with the HPV Challenge, OECD SIDS Program and the ICCA HPV Initiative

Sign up Period and Timeline

Use of Existing Data, Data Adequacy and Preparation of Test Plans

Test Results and Submission of Data

Data Dissemination

Risk Assessment/Risk Management/Risk Communication

International Participation

Role of Enforceable Consent Agreements and/or Rulemaking

APPENDIX I

DESCRIPTIONS OF SELECTED POTENTIAL DATA SOURCES FOR CHEMICAL SELECTION TOOL

Pesticide Inerts:

Pesticide inerts found in pesticide products registered by EPA are identified in four alphabetical lists which contain the name, CAS number and List category for each chemical. The Lists of Inert Pesticide Ingredients are compiled by EPA's Office of Pesticide Programs. List 1 identifies those pesticide inerts which are of toxicological concern. There are 8 pesticide inerts on List 1, at least one or more of which is contained in 160 pesticide products. List 2 includes those pesticide inerts which are potentially toxic and have a high priority for testing. There are 64 pesticide inerts on List 2, at least one or more of which is contained in over 9,000 products. List 3 identifies approximately 1500 pesticide inerts whose potential toxicity is unknown. List 4 includes pesticide inerts which are considered to be innocuous.

National Drinking Water Contaminant Occurrence Database:

The National Drinking Water Contaminant Occurrence Database (NCOD) provides data on the occurrence and concentration of unregulated contaminants in drinking water. NCOD was developed to satisfy the statutory requirements set by Congress in the 1996 SDWA amendments. The purpose of the database is to support EPA's decisions related to identifying contaminants for regulation and subsequent regulation development. The NCOD contains occurrence data from both Public Water Systems and other sources (like the U.S. Geological Survey National Water Information System) on physical, chemical, microbial and radiological contaminants for both detections and non-detects.

NCOD contains occurrence monitoring from sampling locations throughout a Public Water System, therefore a detection value does not necessarily mean the contaminant would be found at the tap. There are some summary statistics, but no actual analysis of the data is provided. Also, NCOD contains data for only unregulated contaminants required to be monitored by public water systems, even though EPA has not set health-based drinking water maximum contaminant levels for this subset of contaminants. This subset is covered by the Unregulated Contaminant Monitoring Rule, or UCMR. Currently the NCOD does not contain occurrence data for all water systems and all states. The only Public Water System data contained in NCOD is data that has been reported by States to the Safe Drinking Water Information System (SDWIS). Historical data goes back to 1983.

Source Ranking Database:

The Source Ranking Database (SRD) contains formulation or emissions data on 1400 chemicals in approximately 12,000 consumer/commercial products. The formulation/emissions data are used, together with parameters such as building volumes and air exchange rates, amount and duration of product use, and chemical properties, to estimate indoor-air concentrations to which people may be exposed in different environments (the current system defines nine environments). The SRD employs four standard scenarios, based on how products/materials are used indoors, to estimate peak and average indoor-air concentrations in each applicable environment for each chemical in the formulation.

Toxics Release Inventory:

The Toxics Release Inventory (TRI) database contains information on the quantity of toxic chemicals released on and off-site into the environment by facilities in the United States that manufacture, import, process, or otherwise use any of the specified chemicals . The TRI, published by the EPA, is a publicly accessible database mandated by Section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA) and Section 6607 of the Pollution Prevention Act (PPA). Section 313 of EPCRA specifically requires facilities that manufacture, import, process, or otherwise use any of more than 600 designated toxic chemicals in excess of threshold quantities to report releases into the air, water, and land. In addition, off-site transfer information must also be reported.

The program applies to industries in the manufacturing sector and those owned by the federal government; therefore, it does not cover all sources of listed TRI chemicals. In addition, facilities that do not meet the TRI threshold levels (those with fewer than 10 full time employees or those not meeting TRI quantity thresholds) are not required to report.

There are a few known problems in the data collection method with the TRI database. Some facilities may not be fully complying with the reporting requirements either by failing to report at all or reporting for only some of their covered chemicals. In addition, TRI requires the reporting of estimated data and does not mandate that facilities monitor their releases.

National Human Exposure Assessment Survey:

The National Human Exposure Assessment Survey (NHEXAS) describes the distribution of human exposure to multiple chemicals from multiple routes and sources on a community and regional scale and its association with environmental concentrations and personal activities. NHEXAS focuses on the comprehensive exposure of people to multiple environmental pollutants from multiple routes and sources to address some of the limitations of single-chemical, and single media exposure route studies. To accomplish this, hundreds of subjects were randomly selected from several areas of the

country and asked to participate. Researchers measured the levels of chemicals in the air participants breathe; in food, drinking water, and other beverages; and in the soil and dust around their homes. Measurements were also made of chemicals in biological samples (including blood and urine) provided by some participants. Finally, participants completed questionnaires to help identify possible sources of exposure to chemicals. NHEXAS in its fullest sense is a conceptual design which utilizes (a) representative sampling (probability-based sampling of a given population), (b) environmental sampling of air, water, soil/dust, (c) personal monitoring of air, food and beverages (duplicate diet) and dermal measurements, (d) biomarkers, and (e) questionnaires.

Aerometric Information Retrieval System:

The Aerometric Information Retrieval System (AIRS) is maintained by EPA's Office of Air and contains the Air Quality Subsystem (AQS) database. AQS contains either one-hour or 24-hour averages of pollutant concentrations from thousands of indoor and outdoor monitoring stations in the United States. The data on pollutant concentration can be ranked by either concentration in air or frequency of observation. The number of different chemicals monitored is not known.

Superfund Contract Laboratory Program:

The Superfund Contract Laboratory Program (CLP) provides data of known and documented quality on soil and water samples in support of EPA's Superfund effort. CLP is a national network of EPA personnel, commercial laboratories, and contractors that since its inception in 1980 has analyzed over 1,850,000 soil and water samples from over 10,000 sites, representing all ten EPA regions and over 430 laboratories. The analyses include 33 volatile organic compounds, 64 semi-volatile organic compounds, 28 pesticide/Aroclor compounds, 23 inorganic compounds, and cyanide. These data are compiled in the CLP Analytical Results Database (CARD). The representativeness of this data may be questionable because all samples are collected from Superfund or other sites that are suspected to be contaminated. CLP data could, however, be considered a conservative representation of sediment/soil and surface/ground water compound concentrations.

National Health and Nutrition Examination Survey III:

The Third National Health and Nutrition Examination Survey (NHANES III) was conducted between 1988 and 1994 on 33,994 people to obtain information on the health and nutritional status of the U.S. population. Several studies (e.g., high blood pressure, immunization status, nutritional blood measures, etc.) were conducted under NHANES III, one of which was the Priority Toxicant Reference Range Study. This Study obtained human biological monitoring data on pesticide metabolites and volatile organic compounds (VOCs) in blood and urine samples. Approximately 670 urine samples were analyzed for 12 pesticide metabolites, and approximately 1,000 blood samples were

analyzed for 32 VOCs. The samples, however, were collected from a non-random (i.e., not statistically representative of the United States) sample size of 1,000 people.

National Adipose Tissue Survey:

The National Adipose Tissue Survey (NHATS) analyzed human adipose (fatty) tissue specimens to monitor human exposure to potentially toxic chemicals. Pathologists and medical examiners from 47 metropolitan statistical areas collected tissue specimens from cadavers and surgical patients during the time period between 1970-1987. These specimens were analyzed for organochlorine pesticides, PCBs, dioxins and furans, volatile organics, semivolatile organics, and trace elements. However, not all compounds were analyzed over the complete time period from 1970 - 1987. Throughout the 1970's and early 1980's the chemical residues of primary interest where organochlorine pesticides and PCBs. During 1982, volatile and semivolatile organic compounds were included in the survey. NHATS was the primary activity of the National Human Monitoring Program (NHMP), operated by the EPA Office of Pollution Prevention and Toxics (USEPA/OPPT), until the early 1990s.

National Occupational Exposure Survey:

The National Occupational Exposure Survey (NOES) was a nationwide observational survey to identify agents to which workers could be exposed. It was conducted on a sample of nearly 5,000 establishments from 1981-1983. The NOES identified approximately 13,766 chemical, physical, and biological agents. Since the NOES database presents information collected from 1981 through 1983, the data are not necessarily representative of the current number of workers potentially exposed to the identified agents. In addition, the data do not provide actual estimates of exposure. NOES data were also collected to characterize management policy and practice in several areas relating to worker safety and health by both industry type and facility size.

Biocentration Factors Data:

Data on Biocentration Factors (BCFs) were derived using the BCFWin Model. The Model estimates the BCF based upon chemical structure and log octanol-water partition coefficients. BCFs are available for more than 103,000 chemicals. Because the data were derived from a model and not empirical studies, the data should be viewed as estimates and not actual values.

Environmental Persistence Data:

The Environmental Persistence Data are a compilation of half-life (air, water, soil, sediment) data in units of hours for more than 103,000 chemicals. The data are derived from various models developed by the Syracuse Research Corporation (SRC) and persistence data from The Environmental Modeling Centre’s Equilibrium Criterion (EQC) Model. The Environmental Modeling Centre (EMC) was established as part of

Environmental and Resource Studies at Trent University, Peterborough, Ontario, Canada in July of 1995. Syracuse Research Corporation (SRC) is an independent, not-for-profit research and development firm chartered by the State of New York. Because the data were derived from models and not empirical studies, the data should be viewed as estimates and not actual values.

The persistence data are derived from the Equilibrium Criterion (EQC) Model, sometimes referred to as the Level 3 Fugacity Model, which is a steady state model using mass transfer coefficients for various media compartments, runoff, deposition, half-life, and other input data to provide general information regarding a chemical's behavior (i.e., partitioning, loss, and transport).

Atmospheric half-lives are derived from the Atmospheric Oxidation Rate Program (AOP), which estimates the reaction rate between organic chemicals and hydroxy radicals. The half-life of a chemical is estimated using an average atmospheric hydroxyl radical concentration and an average atmospheric ozone concentration.

Aqueous half-lives are derived from the Biodegradation Probability Program (BIODEG) using the Ultimate Survey Model output. BIODEG calculates the probability that a chemical under aerobic conditions with mixed cultures of organisms will biodegrade rapidly or slowly. The Ultimate Survey Model was created from the results of a survey of fifty experts who ranked two hundred organic chemicals on their environmental persistence.